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The end of bursectomy for gastric cancer?

Linked commentary for: Bursectomy versus omentectomy alone for resectable gastric cancer: a phase 3, open-label, randomised controlled trial (JCOG1001)

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This well-conducted, multi-centre randomised controlled trial (RCT) makes an important contribution to the surgical management of gastric cancer. It addresses the contentious role of bursectomy. Only one inconclusive RCT has examined this practice previously(1). The present, much larger trial reported by Kurokawa and colleagues resolves the ongoing uncertainty. Bursectomy was associated with a longer operative time, increased blood loss and increased rates of postoperative pancreatic fistula formation, without survival advantage. Bursectomy should therefore no longer be performed routinely in gastrectomy for cancer.

The present trial demonstrated several features key to producing internally valid results(2). Treatment group was allocated centrally after intra-operative tumour assessment to confirm eligibility. Analysis was conducted on an intention-to-treat basis, and survival analysis provided information on censoring of cases according to follow-up at each time point. Outcomes were reported as stated in the protocol, mitigating against reporting bias.

However, some methodological issues have been identified. Neither patients nor outcome assessors were blinded to treatment allocation. This would have been straight forward and would have reduced ascertainment bias, which is especially relevant given the focus on safety outcomes in this study. Another issue is the sample size and power. The study was set to test superiority and powered to test a one-sided hypothesis with only 80% power. This was justified on the basis that bursectomy may increase complications although evidence for this came from the trial itself. Whilst allowance was made for the interim analysis there is concern that the trial is not sufficiently powered to exclude a survival benefit.

In addition, it is important to consider the external validity of this trial, to determine how it ought to shape the practice internationally. The inclusion criteria, focusing on patients with cT3/4 disease and performance status of 0 or 1, provide a broad match to patients undergoing surgery in the UK(3),

although US data suggests patients undergoing surgery there have slightly earlier disease(4). Beyond this, usual clinical practice in the UK and US includes surgery on patients with a performance status of 2, BMI > 30, and insulin-dependent diabetes, who were excluded from this trial(5). Further, routine splenectomy for proximal tumours is not commonly practiced outside Asia. These differences between the trial and more typical Western practice may not fatally compromise the generalisability of this trial's results, but we question whether it was necessary to specify such inclusion and exclusion criteria. Broader inclusion criteria would have maximised the overall utility of trial findings(6).

To participate in the trial, surgeons needed a large volume of experience, with over 100 previous gastrectomies and 20 bursectomies. Surgeons watched videos of both interventions being evaluated in the trial, and photographs of the dissection were taken for every case. This level of quality assurance to minimise performance bias is unusual in surgical trials and should be commended. More information about how the photographs were assessed for surgical quality would have been useful. The level of expertise among the study surgeons should be achievable by surgeons in other countries where gastric cancer surgery has been centralised, but may not be possible where care has not undergone a process of sub-specialisation.

The 5 year overall survival rates in this study were 77% for both intervention groups, which are much higher than survival rates in Western practice(3,4). This marked difference has been reported previously. The difference may have been exaggerated in this study due to exclusion of patients that would be treated in usual practice in the West. This fundamental difference may be a source of concern regarding the application of this trial's findings for many clinicians. In addition, neoadjuvant chemotherapy is common practice in the West. This may influence disease recurrence patterns and outcomes of surgery involving bursectomy, and this study does not include these patients. However,

we consider that the basic oncological considerations regarding bursectomy versus non-bursectomy are likely to apply regardless of these considerations.

In the study's favour, its large, multicentre nature enhances its external validity. The details of perioperative care were not specified in the study protocol and will have varied across the 57 included sites. This will have replicated natural practice variations within a health care system, increasing the applicability of the study findings in other settings.

In summary, this trial is well designed and conducted. While there are some biases and cautions regarding its external validity, we consider that these are unlikely to have significantly compromised the trial result, or its relevance internationally. This trial ought, therefore, to shape practice internationally, promoting a shift away from bursectomy during gastrectomy for cancer while retaining the current gold standard of radical D2 lymphadenectomy.

Conflict of interest statement

The authors declare no conflicts of interest.

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